

Appl. No. : 10/628,380
Filed : July 28, 2003

AMENDMENTS TO THE CLAIMS

1. (Withdrawn) A method of performing a procedure in the heart, comprising the steps of:

providing a catheter having an elongate flexible body, a proximal end, a distal end, and a procedure zone, spaced proximally apart from the distal end;

advancing the catheter antegrade through the mitral valve, through the aortic valve and into the aorta, such that the procedure zone is positioned upstream from the aortic valve; and

performing a procedure from the procedure zone.

2. (Withdrawn) A method of performing a procedure in the heart as in Claim 1, wherein the advancing step comprises advancing the catheter along a guidewire.

3. (Withdrawn) A method of performing a procedure in the heart as in Claim 2, additionally comprising the steps of positioning a flow directed catheter through the mitral valve, through the aortic valve and into the aorta, advancing the guidewire through the flow directed catheter, and removing the flow directed catheter.

4. (Withdrawn) A method of performing a procedure in the heart as in Claim 2, wherein the guidewire is a flow directed guidewire.

5. (Withdrawn) A method of performing a procedure in the heart as in Claim 1, wherein the catheter is a flow directed catheter.

6. (Withdrawn) A method of performing a procedure in the heart as in Claim 1, wherein the advancing step comprises advancing the catheter to position the procedure zone within a flow path between the mitral valve and the aortic valve.

7. (Withdrawn) A method of performing a procedure in the heart as in Claim 1, wherein the procedure zone comprises an opening carried by the catheter.

Appl. No. : 10/628,880
Filed : July 28, 2003

8. (Withdrawn) A method of performing a procedure in the heart as in Claim 2, wherein the opening comprises an opening in a side wall of the catheter.

9. (Withdrawn) A method of performing a procedure in the heart as in Claim 2, wherein the catheter comprises an outer tubular wall having a central lumen, and an inner elongate flexible body extendable through the central lumen, and the procedure zone comprises an opening at a distal end of the outer tubular wall.

10. (Withdrawn) A method of performing a procedure in the heart as in Claim 1, wherein the procedure comprises a diagnostic procedure.

11. (Withdrawn) A method of performing a procedure in the heart as in Claim 1, wherein the procedure comprises a therapeutic procedure.

12. (Withdrawn) A method of performing a procedure in the heart as in Claim 1, wherein the procedure comprises an imaging procedure.

13. (Withdrawn) A method of performing a procedure in the heart as in Claim 1, wherein the procedure comprises a hemodynamic monitoring procedure.

14. (Withdrawn) A method of performing a procedure in the heart as in Claim 1, wherein the procedure comprises an ablation procedure.

15. (Withdrawn) A method of performing a procedure in the heart as in Claim 1, wherein the procedure comprises an atrioventricular valve repair.

16. (Withdrawn) A method of performing a procedure in the heart as in Claim 1, further comprising the step of transluminally advancing the catheter through the intra atrial septum prior to the advancing step.

17. (Withdrawn) A method of performing a procedure in the heart as in Claim 1, wherein the procedure comprises grasping at least one leaflet of the mitral valve.

Appl. No. : 10/628,880
Filed : July 28, 2003

18. (Withdrawn) A method of performing a procedure in the heart as in Claim 1, wherein the procedure comprises attaching the anterior leaflet of the mitral valve to the posterior leaflet of the mitral valve.

19. (Withdrawn) A method of orienting a first and second tissue grasper with respect to the mitral valve, comprising the steps of:

providing a catheter having an elongate, flexible body, with a proximal end, a distal end and first and second tissue graspers spaced apart from the distal end;

transluminally advancing the distal end from the left atrium through the mitral valve and along the left ventricular outflow tract into the ascending aorta; and

positioning the catheter such that the first and second tissue graspers are adjacent the mitral valve.

20. (Withdrawn) A method as in Claim 19, further comprising the step of extending at least the first tissue grasper radially outwardly from the flexible body.

21. (Withdrawn) A method as in Claim 20, wherein the extending step comprises advancing the first tissue grasper from a first position in which a longitudinal axis of the tissue grasper extends generally parallel with the flexible body, to a second position in which the axis is inclined with respect to the flexible body.

22. (Withdrawn) A method as in Claim 20, wherein the extending step comprises advancing the first tissue grasper distally along a pathway which is inclined with respect to a longitudinal axis of the catheter.

23. (Withdrawn) A method of grasping a mitral valve leaflet, comprising the steps of:

providing a catheter having an elongate, flexible body, with a proximal end and a distal end;

transluminally advancing the distal end from the left atrium through the mitral valve and along the left ventricular outflow tract into the ascending aorta;

Appl. No. : 10/628,880
Filed : July 28, 2003

deploying a tissue grasper from a position on the catheter spaced apart from the distal end, and

grasping a mitral valve leaflet using the tissue grasper.

24. **(Withdrawn)** A method of grasping a mitral valve leaflet as in Claim 23, wherein the grasping step comprises piercing the leaflet.

25. **(Withdrawn)** A method of grasping a mitral valve leaflet as in Claim 23, wherein the grasping step comprises trapping the leaflet.

26. **(Withdrawn)** A method of grasping a mitral valve leaflet as in Claim 23, wherein the grasping step comprises applying suction to the leaflet.

27. **(Original)** A catheter for accessing the heart, comprising:
an elongate flexible body, having a proximal end and a distal end;
an anchor zone on a distal portion of the flexible body; and
at least one tissue manipulator carried by the flexible body proximally of the anchor zone.

28. **(Original)** A catheter as in Claim 27, wherein the minimum length of the anchor zone on the distal side of the tissue manipulator is at least about 3 cm.

29. **(Original)** A catheter as in Claim 27, wherein the minimum length of the anchor zone on the distal side of the tissue manipulator is at least about 5cm.

30. **(Original)** A catheter as in Claim 27, wherein the minimum length of the anchor zone on the distal side of the tissue manipulator is at least about 10 cm.

31. **(Original)** A catheter as in Claim 27, wherein the tissue manipulator is moveable between an axial orientation for transluminal navigation and an inclined orientation for manipulating tissue.

Appl. No. : 10/628,880
Filed : July 28, 2003

32. (Original) A catheter as in Claim 27, comprising a first and a second tissue manipulator.

33. (Original) A catheter as in Claim 27, wherein the first tissue manipulator comprises a tissue grasper for grasping a heart valve leaflet.

34. (Original) A catheter as in Claim 27, comprising at least a first component which is axially moveable with respect to a second component.

35. (Withdrawn) A method of performing an atrioventricular valve repair, comprising the steps of:

providing a catheter having an elongate, flexible body, with a proximal end, a distal end, and at least one leaflet grasper thereon;

transluminally advancing the distal end from the left atrium through the mitral valve and along the left ventricular outflow tract into the ascending aorta;

grasping at least a first leaflet of the mitral valve with the leaflet grasper; and

securing the first leaflet to at least one other anatomical structure.

36. (Withdrawn) A method of performing an atrioventricular valve repair as in Claim 35, wherein the securing step comprises securing the first leaflet to a second leaflet.

37. (Withdrawn) A method of performing an atrioventricular valve repair as in Claim 35, wherein the securing step comprises securing the first leaflet to a valve annulus.

38. (Withdrawn) A method of performing an atrioventricular valve repair as in Claim 35, wherein the securing step comprises advancing a suture through the first leaflet.

39. (Withdrawn) A method of performing an atrioventricular valve repair as in Claim 35, wherein the securing step comprises attaching a clip to the first leaflet.

40. (Withdrawn) A method of performing an atrioventricular valve repair as in Claim 35, wherein the securing step comprises attaching a tissue anchor to the first leaflet.

Appl. No. : 10/628,880
Filed : July 28, 2003

41. (Withdrawn) A method of orienting a catheter with respect to the mitral valve, comprising the steps of:

positioning a guidewire from the left atrium through the mitral valve and along the left ventricular outflow tract into the ascending aorta;

advancing a catheter along the guidewire, the catheter having an anchor and a procedure site; and

locating the anchor with respect to an anatomical feature such that the procedure site is at a predetermined orientation with respect to the mitral valve.

42. (Withdrawn) A method of orienting a catheter as in Claim 41, wherein the positioning step includes the use of a flow directed structure.

43. (Withdrawn) A method of orienting a catheter as in Claim 41, wherein the locating the anchor step comprises positioning a distal portion of the catheter within the ascending aorta.

44. (Withdrawn) A method of orienting a catheter as in Claim 41, wherein the locating the anchor step comprises positioning the catheter such that it is approximately centered on the posterior leaflet of the mitral valve.

45. (Withdrawn) A method of performing a procedure in the heart, comprising the steps of:

providing a catheter having an elongate flexible body, a proximal end, a distal end, and a procedure zone, spaced proximally apart from the distal end;

advancing the catheter through the right atrium, through the right ventricle and into the pulmonary artery, such that the procedure zone is positioned at a treatment site;

performing a procedure from the procedure zone.

46. (Withdrawn) A method of performing a procedure in the heart as in Claim 45, wherein the advancing step comprises advancing the catheter along a guidewire.

Appl. No. : 10/628,380
Filed : July 28, 2003

47. (Withdrawn) A method of performing a procedure in the heart as in Claim 46, wherein the procedure is performed on the tricuspid valve.

48. (Withdrawn) A method of performing a procedure in the heart as in Claim 46, wherein the procedure is performed on the pulmonic valve.

49. (Withdrawn) A method of performing a procedure in the heart as in Claim 45, wherein the advancing step comprises advancing the catheter to position the distal end in the right ventricle outflow tract of the pulmonary artery.

50. (Withdrawn) A method of performing a procedure in the heart as in Claim 45, wherein the procedure comprises a valve repair.

51. (Withdrawn) A method of performing a procedure in the heart as in Claim 45, wherein the procedure comprises grasping at least one leaflet of a valve.

52. (Withdrawn) A method of performing a procedure in the heart as in Claim 45, wherein the procedure comprises attaching a first leaflet of a valve to a second leaflet of a valve.

53. (Withdrawn) A method of performing a procedure in the heart, comprising the steps of:

providing a catheter having an elongate flexible body, a proximal end, a distal end, and a procedure zone, spaced proximally apart from the distal end;

advancing the catheter through at least two valves in the heart, through a first chamber in the heart and at least into a second chamber in the heart; and

performing a procedure from the procedure zone.

54. (Withdrawn) A method of performing a procedure in the heart as in Claim 53, comprising advancing the catheter through the mitral valve and the aortic valve.

55. (Withdrawn) A method of performing a procedure in the heart as in Claim 53, wherein the procedure comprises a valve repair.

Appl. No. : 10/628,880
Filed : July 28, 2003

56. **(Withdrawn)** A heart-valve repair apparatus, the apparatus comprising:

a first cardiac catheter having a proximal end, a distal end, a hollow lumen, and two ports, wherein each of the ports communicate with the hollow lumen;

a Valve Immobilization Catheter housed within the first catheter, the valve Immobilization Catheter having a proximal end, a distal end, and comprising

a first leaflet immobilization support and opposite thereto a first fixating member;

a second leaflet immobilization support and opposite thereto a second fixating member;

fastening material having a first end and a second end.

57. **(Withdrawn)** The heart valve apparatus of Claim 56, wherein a receptacle for the first fixating member is within the first leaflet immobilization support and attached to the first end of the fastening material.

58. **(Withdrawn)** The heart valve apparatus of Claim 56, wherein a receptacle for the second fixating member is within the second leaflet immobilization support and attached to the second end of the fastening material.

59. **(Withdrawn)** The heart-valve repair apparatus of Claim 56, wherein the leaflet immobilization supports and fixating members are mounted on a guide wire.

60. **(Withdrawn)** The heart-valve repair apparatus of Claim 57, wherein the leaflet immobilization supports are mounted to the guide wire via a spring.

61. **(Withdrawn)** The heart-valve repair apparatus of Claim 56, wherein the leaflet immobilization supports are positioned towards the distal end of the Valve Immobilization Catheter and the fixating members are positioned towards the proximal end of the Valve Immobilization Catheter.

Appl. No. : 10/628,880
Filed : July 28, 2003

62. (Withdrawn) The heart-valve repair apparatus of Claim 59, whereby moving the catheter in the proximal direction causes the leaflet immobilization supports to emerge from the ports.

63. (Withdrawn) The heart-valve repair apparatus of Claim 56, wherein the leaflet immobilization supports and the ports are positioned towards the proximal end of the Valve Immobilization Catheter and the fixating members are positioned towards the distal end of the Valve Immobilization Catheter.

64. (Withdrawn) The heart-valve repair apparatus of Claim 61, whereby moving the catheter in the distal direction causes the leaflet immobilization supports to emerge from the ports.

65. (Withdrawn) The heart-valve repair apparatus of Claim 56, wherein the Valve Immobilization Catheter further comprises a semi-rigid curved portion as its distal end.

66. (Withdrawn) The heart-valve repair apparatus of Claim 56, wherein the apparatus further comprises an inflatable balloon attached to the distal end of the first catheter.

67. (Withdrawn) The heart-valve repair apparatus of Claim 56, wherein the leaflet-immobilization supports are housed within the Valve Immobilization Catheter, and the Valve Immobilization Catheter is housed within the first catheter.

68. (Withdrawn) The heart-valve repair apparatus of Claim 56, wherein the movement of the first catheter, Valve Immobilization Catheter, leaflet immobilization supports and fixating devices is visualized by fluoroscopy.

69. (Withdrawn) The heart-valve repair apparatus of Claim 56, wherein the movement of the first catheter, Valve Immobilization Catheter, leaflet immobilization supports and fixating devices is visualized by transthoracic echocardiographic visualization.

70. (Withdrawn) The heart-valve repair apparatus of Claim 56, wherein the movement of the first catheter, Valve Immobilization Catheter, leaflet immobilization supports and fixating devices is visualized by transesophageal echocardiographic visualization.

Appl. No. : 10/628,880
Filed : July 28, 2003

71. (Withdrawn) The heart-valve repair apparatus of Claim 56, wherein the movement of the first catheter, Valve Immobilization Catheter, leaflet immobilization supports and fixating devices is visualized by intracardiac echocardiographic visualization.

72. (Withdrawn) The heart-valve repair apparatus of Claim 56, wherein the movement of the first catheter, Valve Immobilization Catheter, leaflet immobilization supports and fixating devices is visualized by echocardiographic visualization.

73. (Withdrawn) The heart-valve repair apparatus of Claim 56, wherein the adequacy of the repair to the heart valve is assessed by fluoroscopy and/or echocardiography.

74. (Withdrawn) A method for repairing a heart valve, the method comprising:
inserting a catheter proximal to first and second leaflets of a heart valve;
engaging the first leaflet of the heart valve with a first leaflet immobilization support;
engaging the second leaflet of the heart valve with a second leaflet immobilization support;
advancing a first fixating member through the first leaflet immobilization support, engaging thereby a receptacle within the first leaflet immobilization support, wherein the receptacle is attached to a first end of fastening material;
advancing a second fixating member through the second leaflet immobilization support, engaging thereby a receptacle within the second leaflet immobilization support, wherein the receptacle is attached to a second end of fastening material;
retracting the fixating members, thereby pulling the fastening material through the leaflets;
withdrawing the catheter, the leaflet immobilization supports, and the fixating members; and
tying off the fastening material.

Appl. No. : 10/628,880
Filed : July 28, 2003

75. **(Withdrawn)** The method of Claim 74, wherein the catheter further comprises an inflatable balloon, and the method further comprises inflating the balloon during the step of inserting the catheter proximal to the first and second leaflets of the heart valve.

76. **(Withdrawn)** The method of Claim 75, wherein the inflated balloon rests in the aortic valve anchoring the catheter.

77. **(Withdrawn)** A method for repairing a cardiac atrioventricular valve comprising:
positioning a leaflet immobilization device across a mitral valve by way of the ventricular outflow tract wherein the ventricular outflow tract orients the leaflet immobilization device so that immobilization of the leaflets will occur without interfering with papillary muscles, chordal structures, or other cardiac structures.